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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,541	06/02/2000	Reiner Gentz	PF402P1	6732

22195 7590 10/27/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	21

DATE MAILED: 10/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/585,541	GENTZ ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-33,36-66 and 71-155* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *74,75,78,79,81,154 and 155* is/are allowed.

6)☒ Claim(s) *1-7,9-33,36-66,71-73,76,77,80 and 82-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Prosecution is Reopened

1. Subsequent to applicant's responses of 10 July 2002 and 24 September 2002 a Notice of Allowance was mailed on 30 September 2002. The US Postal Service returned said Notice of Allowance to the Office and the papers were later matched with the file. The record does not reflect that the Office ever remailed the papers and restarted the period for response. While a Notice of Allowance was mailed, such mailing was without effect due to the return of the papers. Accordingly, the instant application is being treated as the last substantive communication from the Office was the non-final Office action of 14 February 2002.

2. On 17 January 2003 the Office received an Information Disclosure Statement, and on 25 April 2003 another Information Disclosure Statement was received. Both of said Information Disclosure Statements are considered timely under 37 C.F.R. § 1.97(c)(2) as the Statements were received prior to the mailing of a final Office action or a notice of allowance or an action that otherwise closes prosecution.

3. Upon review of prior art submitted in the IDS of 25 April 2003, questions of patentability arose. New grounds of rejection follow.

Oath/Declaration

4. The following is a quotation of the appropriate paragraph of 37 CFR 1.67(b) that forms the basis of the objection under this section made in this Office action:

> A supplemental oath or declaration meeting the requirements of § 1.63 must be filed when a claim is presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented or when an oath or declaration submitted in accordance with §

> 1.53(f) after the filing of the specification and any required drawings specifically and improperly refers to an amendment which includes new matter. No new matter may be introduced into a nonprovisional application after its filing date even if a supplemental oath or declaration is filed. In proper situations, the oath or declaration here required may be made on information and belief by an applicant other than the inventor.

As a result of amendment(s) to the claim(s), the pending claim(s) no longer substantially embrace the invention as set forth in the statement of the invention and/or in the original claim(s). Accordingly, applicant is required to file a supplemental oath or declaration in response to this Office action.

Drawings

5. The drawings filed 06 June 2000 have been accepted by the examiner.

Specification

6. The specification is objected to as documents have been improperly incorporated by reference. See, e.g., page 17, 34, 45, 47, 48, and 71. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun*

> *Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

In the instant case the specification does not state with specificity why these documents are being incorporated and does not specifically indicate where that specific material is found in the various documents. The instant disclosure has, therefore, been considered as though none of the cited documents has been incorporated.

Claim Objections

7. Claims 43, 47, 66, 83, 121, and 125 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

a. Claims 43 and 47 each depend from claim 40. Claim 40 requires that the pharmaceutical composition comprise "a thickening agent in an amount effective to rise the viscosity to about 50 to about 10,000 cps." Claims 43 and 47 effectively broaden the scope of claim 40 in that said claims encompass no thickening agent being present. Such interpretation is based on the lower limitation of "0%" of said thickening agent. Similar issues exist with regards to claims 121 and 125, which depend from claim 118.

b. Claim 1, from which claim 66 depends, set the lower limit of the range of the polypeptide at "about 0.02" mg/ml (w/v). Claim 66 effectively broadens the lower limit by expanding to now include "about 0.01 mg/ml" (w/v).

c. Claim 83 encompasses values of where neither a "chelating agent" nor a "tonicifier" is added (note usage of "0%"). In such an embodiment, the claim does not further limit claim 82.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-33, 36-66, 71-73, 82-150 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

9. For purposes of examination, claims 1 and 82 have been interpreted as encompassing any concentration of preservative.

10. Page 8 of the specification teaches:

> Additionally, the formulations of the present invention may further include one or more preservatives, such as benzyl alcohol, preferably at a concentration of bout 0.5% to about 1.5%, most preferable at a concentration of about 0.9%; chlorobutanol, preferably at a concentration of about 0.01% to about 1%, most preferably about 0.5%; methyl paraben, preferably at a concentration of about0.1% to about 0.2%, most preferably at about 0.18%; propyl paraben, preferably at a concentration of about 0.01% to about 0.05%, most preferably about 0.02%; m-cresol, preferably at a concentration of about 0.1% to about 1%, most preferably about 0.3%; and/or phenol, preferably at a concentration of about 0.1% to about 1%, most preferably at about 0.5%.

The specification has not been found to provide an adequate written description of where other preservative, or where preservatives are to be used outside of the disclosed ranges. Accordingly, the specification does not provide an adequate written description of using any preservative, or specific preservatives at any concentration.

11. Claims 2-7, 9-33, 35-66, and 71-73, which all depend from claim 1, fail to overcome this issue and are similarly rejected.

12. Claims 83-146, which depend from claim 82, also fail to overcome this issue and are similarly rejected.

13. It is noted that claim 73 and 147 recite concentrations of two specific preservatives, however, the claims leave open the inclusion of yet other preservatives at any concentration. It is in this context that claims 73 and 147 have been included in this rejection.

14. Claims 21-24, 27-33, 36-39, 54, 56, 101-104, and 116 have been interpreted as encompassing any "bulking agent."

15. Page 12, lines 12-21, of the disclosure state:

> In addition, bulking agents/cryoprotectants such as sucrose, glycine, mannitol, trehalose or other pharmaceutically acceptable bulking agents are included in the formulation. The amount of bulking agent used will be such that the solution is isotonic and is in the range of about 2% to about 10% w/v. Preferred concentrations are as follows: 5% mannitol,

> 7% sucrose, 8% trehalose, or 2% glycine + 0.5% sucrose. More preferably, sucrose or sucrose/glycine mixture is used.

The specification has not been found to provide an adequate written description of other "bulking agents," nor has the specification been found to provide alternative concentrations at which said bulking agents are to be used in the claimed pharmaceutical composition. Acknowledgement is made of where the specification states that "other pharmaceutically acceptable bulking agents are included in the formulation." Such language is not deemed to constitute an adequate written description of the claimed pharmaceutical composition. It would appear that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

16. Claims 43 and 121 are also rejected under 35 USC 112, first paragraph, for failing to provide an adequate written description of where a thickening agent is present "in a concentration of 0 to 5% (w/v). Such claim language s considered to constitute new matter. For convenience, claims 43 and 121 have been reproduced below.

> Claim 43. The pharmaceutical composition of claim 40, wherein said thickening agent is present in a concentration of 0 to 5% (w/v).

> Claim 121. The pharmaceutical composition of claim 82, wherein said thickening agent is present in a concentration of 0 to 5% (w/v).

17. Page 16, lines 3-10, discloses ranges of thickening agents. The disclosed range of "about 0% to about 5%" is in reference to the presence of sucrose. Sucrose is disclosed as being a "bulking agent" not a "thickening agent." (See specification at page 12, line 12, and also claim 22). Accordingly, claims 43 and 121 are rejected under 35 USC 112, first paragraph, for the introduction of new matter.

18. For purposes of examination, claims 148-150 have been interpreted as encompassing pharmaceutical compositions of virtually any pH. Said claims were added via the amendment of 04 September 2002. Page 6 of the specification states:

> It has been discovered that KGF-2 polypeptides exhibit poor activity and stability at a pH of 4.5 or less, or at a pH above 8.0. The present inventors have discovered that KGF-2 polypeptides oxidize and precipitate. These polypeptides present a difficult challenge when attempting to formulate them for therapeutic uses.

19. In view of such cautionary teachings in the disclosure, the specification has not been found to provide an adequate written description of pharmaceutical compositions comprising said KGF-2 polypeptides where the pH is outside of this disclosed range. Accordingly, the specification does not reasonably suggest that applicant was in possession of the claimed invention at the time of filing.

20. Claims 43 and 121 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

21. For convenience, claims 43 and 121 have been reproduced below.

> Claim 40. The pharmaceutical composition of claim 1, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.
>
> Claim 43. The pharmaceutical composition of claim 40, wherein said thickening agent is present in a concentration of 0 to 5% (w/v).
>
> Claim 118. The pharmaceutical composition of claim 82, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.
>
> Claim 121. The pharmaceutical composition of claim 82, wherein said thickening agent is present in a concentration of 0 to 5% (w/v).

22. As can be seen above, both claims 40 and 118 require the presence of a thickening agent at a concentration sufficient to raise the viscosity of the pharmaceutical composition to within a specified range. Claims 43 and 121 both encompass values where no thickening agent is added. A review of the specification fails to locate a reproducible procedure whereby the claimed pharmaceutical composition and be made and used whereby one satisfies the presence of a thickening agent yet at the same time no such thickening agent is present.

23. Accordingly, and in the absence of convincing evidence to the contrary, said claims are rejected under 35 USC 112, first paragraph, as not being enabled by the originally filed disclosure.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

26. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

27. Claims 1-3, 5-17, 20-32, 36, 37, 71-73, 76, 80, 82-97, 100-115, 144-147, and 151-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Human Genome Sciences, Inc. (WO 96/25422; HGS) in view of Chen et al., (*Journal of Pharmaceutical* Sciences, Vol. 85, No. 4, April 1996) and Prestrelski et al. (US Patent 5,580,856).

28. HGS discloses Keratinocyte Growth Factor-2 (KGF-2), fragments thereof (page 8, last paragraph), and pharmaceutical compositions (page 21). As seen at page 21, the compositions can comprise "saline dextrose, water, glycerol, ethanol, and combinations thereof."

29. HGS does not disclose specific amino acid sequences for the fragments, however, in he absence of convincing evidence to the contrary, one KGF-2 fragments is equally obvious over that of another when as here the prior art explicitly teaches the parent sequence and then directs the ordinary artisan to use fragments thereof as well.

30. Chen et al., page 419, right column, disclose KGF compositions where the concentration of KGF is 0.5 mg/ml, and is in 10mM sodium phosphate buffer. Page 420, left column, discloses using four different buffers: sodium phosphate, ammonium sulfate, sodium citrate, and NaCl.

This disclosure is considered to render obvious the claimed concentration range of KGF polypeptide and buffer, as well as the type of buffer used.

31. Prestrelski et al., column 6, discloses that the pH of buffers used can range from 1 to 13, and that the buffer can citric. Column 6 also discloses using various "additives" (applicant's "preservatives"). Such preservatives include methyl paraben, propyl paraben and chlorobutanol.

32. Column 6, last paragraph, explicitly teaches that such formulations can be applied to Keratinocyte Growth Factor pharmaceutical compositions. Column 8, first paragraph, teaches that the concentration range of the polypeptide "is generally within the range of about 0.05 to about 20,000 micrograms/milliliter."

33. Column 4 discloses incorporating "osmolytes" (applicants' "tonicifier") such as glycine, lysine, trehalose, and sucrose.

34. Column 4, last paragraph, discloses that the compositions can comprise sodium citrate, as well as chelators, including ethylene-diamine tetraacetic acid (EDTA). Bridging to column 5, it is disclosed that the concentration of such agents is preferably between 1 mM to 1 M. Such disclosure fairly suggests the concentration of 125 mM EDTA (claim 11).

35. While the prior art may not explicitly teach certain preferred concentrations of components of the claimed compositions, or the degree to which a composition is lyophilized, such concentrations or dryness, in the absence of evidence to the contrary, are considered obvious through routine experimentation. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

> Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

36. For the above reasons, and in the absence of convincing evidence to the contrary, the pharmaceutical composition of claims 1-3, 5-17, 20-32, 36, 37, 71-73, 76, 80, 82-97, 100-115, 144-147, and 151-153 is rejected under 35 U.S.C. 103(a) as being unpatentable over Human Genome Sciences, Inc. (WO 96/25422; HGS) in view of Chen et al., (*Journal of Pharmaceutical* Sciences, Vol. 85, No. 4, April 1996) and Prestrelski et al. (US Patent 5,580,856).

Conclusion

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

39. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS